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# PolyCath"

CVC 200-60, CVC 200-68 Central Venous Catheter CVC 100-50, CVC 100-65, **Polyurethane** 

# Instructions for Use

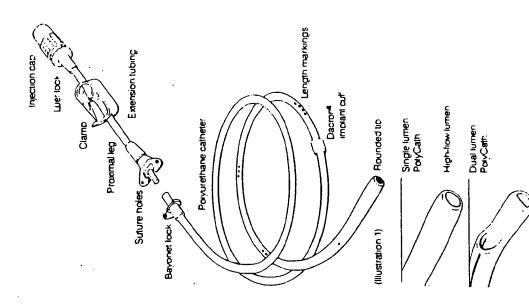
### Introduction:

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The Poly Cath is a boyurethane central vendus dathers used ior access of the venous vascular system

### Description:

distal tp. The catheter terminates in an attachable clear silicone extension assembly that is equipped with a locking connector aual lumen central venous catheter \* ..e PolyCath catheter is radiopadue. ant polyurethane that softens after with length markings. Dacrone implant cutt and a rounded ciamp, luer toc. and injection cap (see litustration 1) The PolyCath single an is made of thrombore. insertion into the veir.



# Specifications:

• TyDe	Smgle iume:	เปราเยา	Co.o.	Gual rumer
			LCC)	(Condie-D
<ul> <li>Introduce: Size</li> </ul>	9 French	nor.	₽	10 Frenct
<ul> <li>Inside Diameter</li> </ul>	1.6mm	דור	14mm (eouware	guivais
<ul> <li>Outside Diameter</li> </ul>	2.6mr	ji.	3.2	Sann
• Length	€5 cm	50 cm	9€ ст. 6€ ст	<u>ون</u> ن
Priming Volume				
Catneter.	:3 E	1.0 H	E	2,
<ul> <li>Priming Volume</li> </ul>				
Extension	.22ml/	.22т/литег	22ml	22ml/iume*
Materiai				
Catheter.	Poivure	Poivurethane	Povur	Poivurethan€
Extension	Silicone	one	Sign	Silcone
SQ.	Dacron	ن يون	ည သ	Dacron
	(Poweste	Coivester Fabric.	Convester Facin	er Face

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Length markings are located even. 5 cm up to 20 cm irom the dista! IID

## How Supplied:

The PolyCath is backaged sterile in an introducer kit tray which

- Peer away sneath infroduce, and diractor naudes the following
  - · 10ml syringes
- 038 inch diameter × 76 cm long "" wire
  - Disposable scalpe:
    - CSR wrac
- Surgical drade
- Stainless stee: tunneling trocar
- 18 gauge'2 inch extra thin wa: needle • Gauze bads 4 x 4 inct.

  - 22 gauge needles

- Foam swabs

  - Injection caps

## Indications for Use:

The PoivCath catheter is indicated for ballent therapy reduining medications, parenteral solutions, parenteral nutrion solutions acute or long term central venous access tor the infusion c or blood products and for the withdrawaro! brood samples

## Contraindications:

The PolyCath catheter is contraindicated for datient

- The presence of intection, bacteremia or septicemia is known. Ineraby wnenever.
  - The ballent is know or suspected to have an allergic readilon to materials contained in this device of has exhibited a Drict or suspected
- known or suspected to have adverse reactions with mater als · Medications, nutritional products or other substances are IMDIERANCE TO IMDIANTED DEVICES

### Potential Complications: used in this device

Use of the PoivCath catheter involves risks normally associated with percutaneous vengus introduction procedure, vendus quidown procedures and bost-surgical recovery<sup>1,2</sup>

Cameler occiusion, damage or breakage can occur due to Dinch-of" by crimping action of the first ric and clavicie Cameler shearing has been reported when the calheter is inserted via a more media route in the subclavian vein 🤅

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documented.6

In addition the following items are potential complications:

 Catneter malposition, occlusion, fibrin sheath formation at trp. rupture, erosion, and disconnection

Exit site infection

Subcutaneous tunnel infection

Hemorrhage

Pneumothorax, hemothorax or hydrothorax Vascular thrombosis

Hematoma .

Air embolism

Vessel trauma

Cardiac tamponade

Perforation or taceration of vessels or right atrium

Endocarditis

Intolerance to implanted device

Caution:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Read instructions thoroughly before use

 Contents of package are sterile and non-pyrogenic unless damaged or opened

This device is intended for single use only. Do not resterlize

# Warnings and Precautions:

be exposed to prolonged contact with alcohol, alcohol · The polyurethane portion of this catheter should not containing substances, or acetone.

The PolyCath catheter is to be inserted, manipulated and removed only by a qualified licensed physician.

these instructions do not represent all the medically accepted The medical techniques and procedures recommended in protocols and the physician should use his expenence and judgement in determining the acceptable treatment for the patient

Do not clamp the tubing with forceps or sharp instruments Use sterile technique when handling or using the catheter

Do not nick or cut the catheter or extension assembly.

 The catheter must be filled with saline or an isotonic fluid before insertion to prevent an embolism.

Catheter must be flushed after blood withdrawals and injections to prevent blockages.

medical personnel should be familiar with and observe al! warnings, cautions, contraindications and instructions as specified by the manufacturer of the infused substance Prior to infusion of any substance through the catheter,

Confirmation of catheter placement by x-ray or fluoroscopy is recommended

# Catheter Placement:

or blunt needle before placement. Refer to your institutions The catheter must be flushed and filled with intravenous saline or heparinized saline waithe extension assembly protocol for determining the hepenn concentration 1. Preparation

 Check catheter for flow and patency and usage

# 2. Catheter Placement

 By surgical culdown or percutaneous introduction position the distal end of the catheler at the desired site.

Confirm catheter placement by x-ray or fluoroscopy.

Using the tunneling trocar create a tunnel to the desired

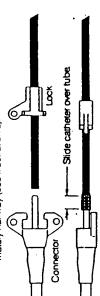
Allow for proper placement of the Dacron cuff.

 The catheter transition from the veriponcture site to the exit ste should be smooth and not kink the catheter

## Catheter Assembly

Inm the catheter and slide the bayonet locking ring over

 Slide the catheter over the connector outlet tube(s) approximately halfway (see Illustration 2). the catheter.



 Slide the bayonet locking ring onto the connector outlet until it contacts the connector body.

flush with the connector base thereby locking the catheter Turn the bayonet locking ring 90° until the sulure tab lies in place.

Catheter should be visible between the connector and

 The dual lumen connector (not shown), follows the same assembly technique

A suture may be used to secure lock to connector.

## 4. Flow Verification

Aspirate blood through the catheter to assure patency.

heparinized intravendus saline according to your institu- Imgate the catheter tumen(s) with intravenous saline or tions protocol

· Attach injection cap(s).

Secure the venipuncture and exit site as necessary.

# Access and Maintenance Procedures:

 Attach a sterile 22 gauge × 1" needle to a 10ml synnge containing 5ml of steme saline for injection. 1. Routine Flush Recommendations:

Using aseptic technique, per institutional protocol, prepare the injection cap which is secured to the PolyCath catheter Inject the saline through the injection cap of the catheter.

### Maintenance

tions, it is recommended that this procedure be performed When the catheter is not being used for infusions or injecper institution protocol

with hepannized saline solution when not being utilized for The internal lumen of the PolyCath catheter must be filled

 A saline flush must always be performed following an infusion or injection of solutions or

### 3. Aspiration.

 After the withdrawal of a blood sample, vigorously flush the there is no visible blood in the catheter or the injection cap. catheter with 10-20ml of sterile saline for injection until

 If blood remains visible within the injection cap, replace the cap using aseptic technique.

### User Checklist

Do not expose the polyurethane to acond

Use aseptic technique at all times.

Use only a 10ml or larger size syringe.

Use only solutions that are compatible with the catheter

materials.

 Be sure saime or heparinized saline remains within the internal Never exceed 25 PSI pressure in the device.

lumen of the catheter at all times when not in use Flush the catheter after each infusion or injection

 It is recommended that a 20 gauge by 1\* needle or smaller is utilized for insertion into the injection cab.

Do not clamp tubing with forceps.

### References:

1 Selonger St. Catheter repracement of the needte in perculaneous amenography, Acta Radiotica 1953, 39,368

Littleford PO., Spector D.S. Device for the rapid insertion of a permaneril endocardial pacing electrode Inrough the subclavian vern

preiminary report. Annai Thoracic Surg 1979, 27 265 3. Atken DA. Mirton JP. The : pinch-off sgn." A warning of impending problems with permanent subdavian catheters. Am J Surg 1984 Achardson JC, Grover FL, Trinde JK. Intravendus catheter embol. Experience with twemy cases and collective review. AM J Surg. 1374.

Robenstein RB, Alberty RE, Michels LG, Pederson RW, Rosentral D. Hickman catheter separation J Parent Ent Nutr. 1985, 9:354 6 Fisher RG, Ferreyro P. Evaluation of current techniques for non-

Surgical remova of intravascular latrogenic foreign bodies. Am J Roentgenoi 1978, 130,548

### Information:

For further information call or write



Strato Medical Corporation Toll Free 800-637-5006 123 Brimbal Avenue Beverly, MA 01915 508-927-9419

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Printed in U.S.A. C.1990 Shitto Medical Corporation PN132260 Rev A



### Visual Reference Guide for the Placement of the Diatek® Cannon™ Catheter

This brochure does NOT supply complete information for the use of this product. See the Instructions for Use (PN60004) supplied with each Diatek Dialysis Catheter for additional information including Caution and Warning statements that apply to the device.

Federal Law (USA) restricts the device to sale by or on the order of a physician.

The Cannon ™ Catheter is intended for single use only.

Do not re-sterilize the catheter or accessories by any method.

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E-Mail: info@diatekinc.com

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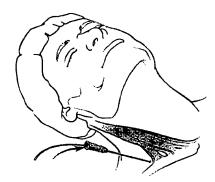
1. Attach irrigation tube to the catheter.



2. Flush and clamp the catheter.



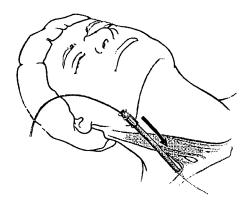
3. Access vessel and determine appropriate catheter length.



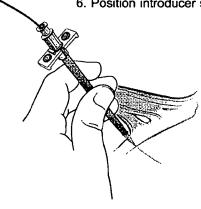
4. Create catheter pocket using blunt disection.



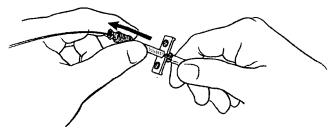
5. Dilate vessel.



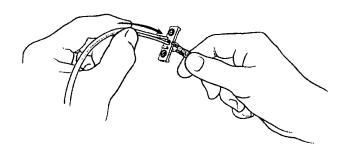
6. Position introducer sheath.



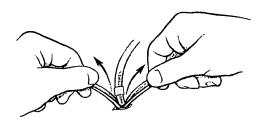
7. Remove dilator from sheath and occlude.



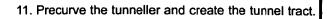
8. Place catheter through sheath into vessel

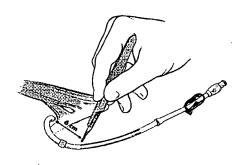


9. Remove peel-away sheath. Verify that the tips are in the right atrium.

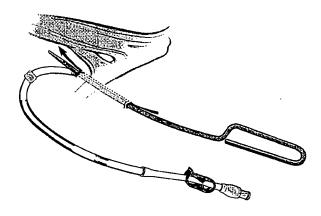


 Position catheter on the chest with a gentle curve, locate exit site mark on catheter (next to cuff) and make a small incision.



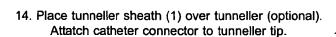


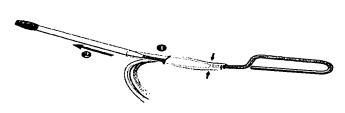
12. Dilate the tunnel tract. Do not pass through the exit site



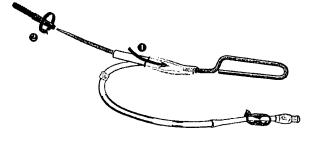
13. Insert to cuff position (1) Remove the dilator (2).



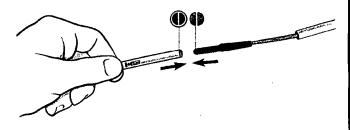




15. Clamp catheter proximal to the cut line and remove irrigation tube. Align prongs of the catheter connector and attatch.



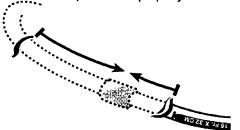
16. Slide tunneller sheath over connection (optional).



17. Gently pull the catheter through the tunnel tract.



18. Use the exit site mark on the catheter to assure that the cuff is positioned properly.



19. Remove tunneller and sheath from the catheter connector .



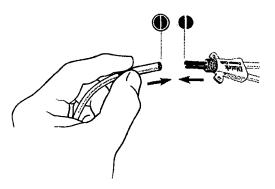
20. Place compression adapter and sleeve onto the catheter.



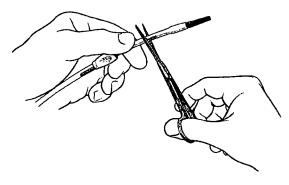
22. Align the catheter with the connection assembly

(red to red and blue to blue).

Push the catheter conpletely onto the cannula.



21. Pinch the catheter and cut at the cut line.



23. Slide the compression adapter forward, with the sleeve inside.



24. Screw the compression adapter onto the threaded section of the connection assembly until no threads are visible. Do not over tighten.



25. Secure the catheter to the skin using the suture wings.

